STEVEN L BESHEAR
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES
RADIATION HEALTH BRANCH
275 EAST MAIN STREET, HSIC-A
FRANKFORT, KENTUCKY 40621-0001
(502) 564-3700 (502) 564-9742 FAX

JANIE MILLER
SECRETARY

April 12, 2010

Representative Edward J. Markey
Chairman
Subcommittee on Energy and Environment
Congress of the United States of America
Committee on Energy and Environment
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Representative Markey:

Attached is the Commonwealth of Kentucky, Cabinet for Health and Family Services, Radiation Health Branch's response to your request for information dated March 18, 2010 regarding the oversight and treatment of patients with radio isotopes.

If you have any questions or if we can be of any further assistance, please do not hesitate to have your staff contact Michele Greenwell, CNMT of my staff at 502-564-3700, extension 4515.

Sincerely,

Dewey F. Crawford, BS, RT (R) (N)
Radiation Control Program Administrator
Radiation Health Branch

c: William D. Hacker, MD, FAAP, CPE
Commissioner Department of Public Health

Guy F. Delius, RS, Director
Division of Public Health Protection and Safety

Commonwealth of Kentucky's Response to Congress of the United States, House of Representatives, Committee on Energy and Commerce. Letter Dated March 18, 2010

1. How many I-131 licensee facilities are overseen by your state?

   There are currently 55 facilities, in the Commonwealth of Kentucky, licensed to perform therapeutic treatment with I-131. Of the 55 licensed facilities, 16 licensees administer therapeutic treatment with I-131 greater than 33 mCi.

2. How often does your State perform sampling inspections each of these I-131 licensee facilities?

   Of the 55 licensed facilities, three of the licensees are Broad Scope Licenses (As defined in the Kentucky Administrative Regulations (KAR), 902 KAR 100:052 (Attachment 1). These licensees are inspected on an annual basis. The remaining 52 facilities are inspected on three-year intervals.

3. What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

   The inspection of a Radioactive Material License (RAML) authorized for therapeutic treatment of I-131 greater than 33 mCi is based on the licensee's license agreement and KAR. A guide and the requirements to be issued a RAML can be accessed at the following web site http://chfs.ky.gov/dph/radioactive.htm. A GUIDE FOR THE PREPARATION OF RADIOACTIVE MATERIAL LICENSE APPLICATIONS FOR MEDICAL PROGRAMS, (Attachment 2, Appendix K, T, and Exhibit 7.) and 902 KAR 100:072, Sections 13., 22., 27., 33., 34., 35., and 73.(Attachment 3) The medical licensing guide and KARS are as strict as NUREG-1556, Vol. 9.

   During an inspection, the licensee's practices are reviewed and observed to ensure they are compliant with their license agreement and KAR. During the inspection, the inspector uses a standard inspection form for medical radiopharmaceutical therapy licensees. (Attachment 4) The inspection is "performance based". This type of inspection includes having the licensee perform various duties associated with their license agreement, review of records, and documentation the licensee is required to record and maintain. Records involving therapeutic use of I-131, less than or greater than 33 mCi, are required to be retained for 3 years after the date of release of the patient treated with therapeutic I-131. These records are required to be available for review by the Commonwealth of Kentucky at anytime.

4. NCRP 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients." For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

   A GUIDE FOR THE PREPARATION OF RADIOACTIVE MATERIAL LICENSE APPLICATIONS FOR MEDICAL PROGRAMS, (Attachment 2, Appendix K and Exhibit 7.) 902 KAR 100:072, (Attachment 3, Sections 27., 34., and 35.), provide guidelines and requirements of licensees who administer therapeutic doses of I-131 greater than 33 mCi to individuals that can be released from the medical facility or must be treated as an inpatient. (Patients treated with larger amounts of I-131 that require hospitalization can be released when the activity level of the I-131 administered has reached the level for release allowed by NUREG-1556, Vol. 9.) These regulations contain information regarding acceptable patient specific dose calculations for the therapeutic dose of I-131 administered and radiation safety precaution instructions that must be provided to the patient for safe post therapeutic procedures to ensure protection, for members of the public from unnecessary radiation exposure from the patient.

   Before a RAML is issued for therapeutic use of I-131 greater than 33 mCi, the licensee must agree to educate the patient on radiation safety precautions to follow post therapeutic dose. Education provided to the patient is reviewed during inspections of the RAML. (Attachment 5.Radiation Safety Precautions provided by some Medical RAML in the Commonwealth of Kentucky to patients receiving therapeutic doses of I-131 greater than 33 mCi.)

5. In the past ten years, how many times has your State, as part of the inspections it conducts, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?

   Licensees are required to follow NUREG-1556, Vol. 9 for determination of individual patient's safe release following therapeutic doses of I-131 greater than 33 mCi. Inspections of licensees are considered "performance based". This type of inspection includes observation of licensees performing procedures, review of records, and

documentation of therapeutic doses of I-131 greater than 33 mCi. (Attachment 6, patient specific dose calculations used by some Medical RAML in the Commonwealth of Kentucky during inspections.) These records are required by the RAML agreement and KAR to be retained for 3 years after the date of therapeutic treatment with I-131 for individuals receiving therapeutic doses of I-131 greater than 33 mCi. These records are required to be available for review by the Commonwealth of Kentucky at anytime.

Current KAR contains no requirement for continued monitoring of patients post administration of therapeutic doses of I-131 greater than 33 mCi.

During inspections and review of documentation we have never seen records that indicate the patient has been instructed to stay in a hotel post administration of a therapeutic dose of I-131 greater than 33 mCi. We are unaware of any patients being released to stay in a hotel.

6. In the past ten years how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?

   During an inspection the licensee is requested to provide copies of the documentation patients receive prior to a therapeutic dose of I-131 greater than 33 mCi. (Attachment 5) Records of administered doses of I-131 greater than 33 mCi are also reviewed to ensure correct dose calculations have been used. (Attachment 6) Orders authorizing and verifying the treatment have been reviewed and signed by the authorized user and the patient has signed indicating they have received radiation safety precautions and procedures to use following administration of the I-131 therapeutic dose.

7. In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

   We have not encountered problems with individualized analysis and/or dose calculations used or guidance provided to the patient by the licensed facility. Our licensees must agree to use NUREG 1556, Vol. 9 guidance for individualized analysis and/or dose calculations for patients. (Attachment 2, Section 27, (1) Licensees use computer programs based on NUREG 1556, Vol. 9, to perform individualized analysis. (Attachment 6)

8. In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

   We agree. We are unaware of any authorized licensees in the Commonwealth of Kentucky that instruct patients to go to a hotel after therapeutic administration of I-131 greater than 33 mCi. There is no KAR that allows for continued monitoring of the patient that has been released under the requirements of NUREG 1556, Vol. 9.

   Patients going to hotels post therapeutic administration of I-131 greater than 33 mCi may make the decision based on their personal needs. The radiation safety precautions provided to the patient requiring them to have limited close contact with small children could be difficult for patients with younger children. The authorized user that treated the patient would not know the patient has chosen to stay in a hotel post treatment.

9. Has your state ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so please provide the results. If not, why?

   a) Patients who receive therapeutic doses of I-131 greater than 33 mCi that meet NUREG 1556, Vol. 9, requirements for release are sent home in most cases unless there is another medical condition requiring hospitalization. Most insurance companies will not authorize the hospitalization for patients receiving therapeutic doses of I-131 greater than 33 mCi if their release is within the guidelines of NUREG 1556, Vol. 9.

   b) When NUREG 1556, Vol. 9., was established the Commonwealth of Kentucky had several medical RAML holders that administered therapeutic doses of I-131 greater than 33 mCi who wanted to continue hospitalization of the patient receiving therapeutic doses that are now be eligible for release under NUREG 1556, Vol. 9. Several insurance companies would no longer authorize inpatient treatment. There were meetings with the former Radiation Health Branch Manager, Health Physicist in the Commonwealth of Kentucky, the medical RAML holders and prominent insurance providers for patients of the licensees. The insurance companies made the decision to deny authorization for hospitalization if the patient's therapeutic dose of I-131 greater than 33 mCi met the criteria for release under NUREG 1556, Vol. 9.

c) We are unaware of any licensed facilities releasing patients to a hotel after receiving a therapeutic dose of I-131 greater than 33 mCi. If a patient chooses to stay in a hotel after a therapeutic dose, it is most likely their decision.

d) Most insurance companies will not authorize hospitalization stays for patients who receive therapeutic doses that meet the criteria for patient release under the guidance of NUREG 1556, Vol. 9.

10. In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.

    Any patient receiving a therapeutic dose of I-131 greater than 33 mCi in the Commonwealth of Kentucky are required to have analysis of their living circumstances before administration of the therapeutic dose of I-131. RAML issued to any facility requires analysis of living circumstances of the individual being treated by the licensee administering the therapeutic dose of I-131 greater than 33 mCi. If the determination is made that the individual cannot adhere to the guidelines in their living circumstances, therapeutic administration of I-131 greater than 33 mCi will be delayed. Authorization for hospitalization would most likely be requested from the patient's insurance company.

11. What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?

    The Commonwealth of Kentucky is unaware of any licensees releasing patients with instructions to stay in a hotel following therapeutic administration of I-131 greater than 33 mCi. There is no KAR that allows the Commonwealth of Kentucky to monitor or restrict patients who have been released. KAR requires the patient be provided with radiation safety instructions to follow after treatment with I-131 greater than 33 mCi. The patient is relied on to be compliant and follow the radiation safety instructions.

12. Has your state ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.

    We have never issued an advisory or guidance to licensees regarding release of patients to hotels.

13. Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?

    There is no KAR requiring the monitoring of a patient that has been released post therapeutic administration of I-131 greater than 33 mCi. A licensee will most likely never know if a patient has exposed family members or members of the public to unsafe radiation levels. Patients are given specific radiation safety instructions when they leave the medical facility. If the patient is not compliant and does not follow the instructions, the licensee would have no way of knowing.

    If the licensee became aware of such an exposure, they would be required to follow the instructions in 902 KAR 100:019, Sections 39. and 40 and/or 902 KAR 100:072, Section 17. (Attachment 7)

14. Please provide copies of all correspondence, including emails, letters, meetings or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radio-nuclides.

    There is no current correspondence with the NRC and the Commonwealth of Kentucky related to the release of patients who have been treated with I-131 greater than 33 mCi.

15. Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If you sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

    In the past five years of inspections, we have not encountered any problems with documents relating to patient release missing, inadequate, or unclear during the course of a sampling inspection. We are unaware of licensee's knowledge of patients going to a hotel after treatment.

APPENDIX T

WRITTEN DIRECTIVES
(902 KAR 100:072, Sections 13 & 14)

A written directive must be dated and signed by an authorized user before the administration of I-131 greater than 30 microcuries, any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record.

A written directive must be prepared within forty-eight (48) hours of the oral directive.

A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record.

A revised written directive must be signed by the authorized user within forty-eight (48) hours of the oral revision.

The licensee shall retain a copy of the written directive for three (3) years.

For any administration requiring a written directive, the licensee shall develop, implement and maintain written procedures to provide high confidence that:

- The patient's or human research subject's identity is verified before each administration, and
- Each administration is in accordance with the written directive

A licensee shall retain a copy of the written procedures for the duration of the license.

The following are elements for consideration when developing written procedures. Some may or may not apply to your facility. The requirements of 902 KAR 100:072 sections 13 and 14 should be carefully reviewed and incorporated into any written procedures.

Elements pertinent to all therapies requiring a written directive

Prior to administration, a written directive issued by an authorized user will be prepared A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

1. Patient's name
2. Patient identification number, if available
3. Radiopharmaceutical
4. Dosage
5. Route of administration
6. The type of procedure desired
7. Date
8. Signature of authorized user

Prior to administration, the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the administration will complete the verification. Verification of identity must include at least two of the following methods:

1. The patient shall be asked to state and spell their name.
2. The patient shall be asked to state their birth date.
3. The patient shall be asked to state their social security number.
4. The patient shall be asked to state their address.
5. The patient shall be asked for identification, i.e. driver's license.
6. The patient's wrist identification band shall be checked for name and patient number.
7. For patients unable to respond, an accompanying relative or friend may attest to the patient's identity. Record name and relationship of same.

If the information obtained from any two of these methods does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification is obtained.

Oral directives are permissible only when a patient's medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is documented in writing as soon as possible in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. (See 902 KAR 100:072, Sections 15 &16)

An annual review should be conducted to ensure compliance and effectivness.

Elements pertinent to the use of I-131 or any other therapeutic dosage of unsealed radioactive material

Each administration must be in accordance with the written directive. The physician or nuclear medicine technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

Each administration must have a written protocol. A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures performed which require written directives. A procedure, which requires a written directive, shall not be initiated until a written protocol approved by an authorized user is available. The nuclear medicine physicians and technologists shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them. The protocol shall contain the following elements:

1. Pharmaceutical
2. Radionuclide
3. Routine dosage
4. Route of administration
5. Indications
6. Contraindications

Any change in protocol shall be approved by an authorized user before that change is implemented and always before the change is incorporated into the procedure manual. Each person who prepares and administers radiopharmaceuticals shall be instructed in the change before it is implemented or incorporated into the procedure manual.

Following administration of the radiopharmaceutical dose, a dated and signed written note is entered into the patient's record documenting the administration and dosage.

Elements pertinent to a therapeutic dose of radiation from radioactive material

Each administration must be in accordance with the written directive. A qualified individual shall read the written directive before preparing or administering the brachytherapy dose. A qualified individual includes radiation therapy physicist, oncology physicians, dosimetrists, or radiation therapy technologists. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The brachytherapy dose shall not be administered until the intent of the written directive is thoroughly understood by the personnel administering the dose. The specific details of the treatment plan shall be verified with the written directive by a qualified individual.

Radiographs or other comparable images (e.g., CT images) made with either the brachytherapy sources or non-radioactive "dummy" sources in place should be used as the basis for verifying the positions of the sources and calculating the treatment time. The use of dummy sources are preferred over active ones whenever possible. It is recognized that such images may not be necessary in certain procedures in which applicators are used, provided the source positions are known prior to inserting the active sources and calculating the treatment time.

After insertion of either permanent or temporary brachytherapy sources an authorized user will promptly record the actual loading sequence of the radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

During the implant or loading procedure, the end of any tubing containing radioactive sources must be positioned and secured in such a way as to minimize the possibility of accidental dislodgment. The patient is observed frequently by nursing personnel to verify that the sources remain in position as loaded for the duration of the treatment period.

Before the total prescribed brachytherapy dose has been delivered, an authorized user, or a qualified individual under the supervision of an authorized user, (other than the person who made the original calculations, if possible), shall check the dose calculations. Manual dose calculations should be checked for arithmetic errors; appropriate transfer of data from the written directive, plan of treatment, tables and graphs; appropriate use of nomograms (when applicable) and appropriate use of all pertinent data in the calculations.

Computer generated dose calculations shall be checked by examining the computer printout to verify that the correct data for the patient was used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Alternatively, the brachytherapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer generated outputs (or vise versa), particular emphasis should be placed on verifying the correct

output from one type of calculation (e.g., computer) to be used as an input in another type of calculations (e.g., manual).

NOTE: If the authorized user determines that delaying treatment in order to perform checks of dose calculation would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations shall be performed within two working days of completion of the brachytherapy treatment.

An authorized user must date and sign a written record in the patient's chart after insertion of the brachytherapy source but prior to completion of the procedure. The written record shall include the radionuclide, treatment site, total source strength and exposure time (or equivalently, the total dose).

Acceptance testing will be done by a qualified individual on each treatment planning of dose calculating computer program that can be used for brachytherapy dose calculations. Acceptance testing will be performed before the first use of a computer program for brachytherapy dose calculations. A written record shall be kept documenting the results of the acceptance tests.

Subsequent to the loading of brachytherapy sources, an authorized user or other qualified individual shall verify that the written directive was followed in terms of the number of sources implanted, the source strengths and the source positions. The treatment time will be reaffirmed at this time. In some instances, the authorized user may determine that radiographic procedures are required to confirm proper source positioning.

EXHIBIT 7

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY OVER 33 MILLICURIES

Patient: _____ Room: _____ Date _____

PREPARATION

____ Schedule a private room, with private sanitary facilities and without carpet, in a low traffic area.
____ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
____ Prepare labeled boxes for used linen, disposable waste, and non-disposable contaminated items.
____ Prepare urine collection containers if urine will be collected.
____ Stock room with disposable gloves, absorbent paper, and "radioactive waste" labels.
____ Mark a visitors' "safe line" on the floor.
____ Order disposable table service.
____ Notify housekeeping to not clean the room until further notice.
____ Brief the nursing staff on radiation safety measures.
____ Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION

____ Clear the room of unneeded personnel.
____ Brief the patient on the clinical procedure.
____ Administer the dosage.
____ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
____ Post the room with a "Radioactive Materials" sign.

FOLLOW-UP

____ Measure the thyroid burden of all personnel who were present for the administration.
____ Pick up waste for decay-in-storage or decontamination.
____ Release the patient.
____ Decontaminate and survey the room. Remove the "Radioactive Materials" sign.
____ Call the Housekeeping Office to clean the room.

902 KAR 100:052. Broad scope licenses.

RELATES TO: KRS 211.842-211.852, 211.990(4)
STATUTORY AUTHORITY: KRS 194.050, 211.090, 211.844
NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Human Resources is authorized by KRS 211.844 to provide by administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation prescribes requirements for the issuance of specific licenses of broad scope for radioactive material.

Section 1. Applicability. This administrative regulation establishes requirements for specific licensees to possess, use or transfer radioactive material for licenses of broad scope.

Section 2. Types of Specific Licenses of Broad Scope. (1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in 902 KAR 100:090, relating to broad license quantities, for any authorized purpose. The possession limit for a Type B broad license, if only one (1) radionuclide is possessed, is the quantity specified for that radionuclide in Column I of the table in Section 2 of 902 KAR 100:090. If two (2) or more radionuclides are possessed, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column I of the table in Section 2 of 902 KAR 100:090 for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in 902 KAR 100:090, relating to broad licensed quantities, for any authorized purpose. The possession limit for a Type C broad license, if only one (1) radionuclide is possessed, is the quantity specified for that radionuclide in Column II of the table in Section 2 of 902 KAR 100:090. If two (2) or more radionuclides are possessed, the possession limit is determined for each as follows: for each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Column II of the table in Section 2 of 902 KAR 100:090 for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

Section 3. Requirements for the Issuance of a Type A Specific License of Broad Scope. An application for a Type A specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 902 KAR 100:040;

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) The applicant has established administrative controls and requirements relating to organization, management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) The establishment of a radiation safety committee composed of persons, such as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials;

(b) The appointment of a radiation safety officer who is qualified by training and experienced in radiation protection, who is available for advice and assistance on radiological safety matters; and

(c) The establishment of appropriate administrative procedures to assure control of procurement and use of radioactive material; completion of safety evaluation of proposed uses of radioactive material which take into consideration matters, such as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with this subsection prior to use of the radioactive material.

Section 4. Requirements for the Issuance of a Type B Specific License of Broad Scope. An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 902 KAR 100:040; and

(2) The applicant has established administrative controls and provisions relating to organization, management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, who is available for advice and assistance on radiological safety matters; and

(b) The establishment of appropriate administrative procedures to assure control of procurement and use of radioactive material; completion of safety evaluations or proposed uses of radioactive materials which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, the operating or handling procedures; and review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with this subsection prior to use of the radioactive material.

Section 5. Requirements for the Issuance of a Type C Specific License of Broad Scope. An application for a Type C specific license of broad scope shall be approved if:

(1) The applicant satisfies the general requirements specified in 902 KAR 100:040;

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(a) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering;

Attachment 1

(b) At least forty (40) hours of training and experience in the safe handling of radioactive materials, characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

Section 6. Prohibited Acts and Conditions for Specific Licenses of Broad Scope. (1) Unless otherwise specifically authorized by these administrative regulations, persons licensed under this administrative regulation shall not:

(a) Conduct tracer studies in the environment involving direct release of radioactive material;

(b) Receive, acquire, own, possess, use, or transfer, devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

(c) Conduct activities for which a specific license issued by the cabinet under 902 KAR 100:051 or 902 KAR 100:058 is required; or

(d) Add or cause the addition of radioactive material to a food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under this administrative regulation shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under this administrative regulation shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this administrative regulation shall be subject to the condition that radioactive material possessed under this license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of Section 5 of this administrative regulation. (6 Ky.R. 219; eff. 12-5-79; Am. 12 Ky.R. 1033; eff. 1-3-86; 18 Ky.R. 1513; eff. 1-10-92.)

APPENDIX K

MODEL PROCEDURES FOR THE SAFE USE OF
RADIOPHARMACEUTICALS IN THERAPY
(902 KAR 100:072, Sections 27, 34 and 35)

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix K to Medical Programs Licensing Guide, Revised April 2005."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:072, Sections 27, 34, and 35.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

   a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, doorknobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

   b. Prepare separate boxes for linen, disposable waste, and non-disposable contaminated items. Place a single large resealable plastic bag in each box, or supply several small plastic bags.

   c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.

      (1) Containers should be unbreakable and resealable.

      (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

      (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper.

      (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

Attachment 2

(5) Supply a wide-mouth anti-splash funnel.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges or TLDs.

5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131, Phosphorus-32, or Gold-198" (Exhibit 6), or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in 902 KAR 100:019, Section 10). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter sign out form. Post the room with a "Radioactive Materials" sign.

10. For patients treated with liquid or gelatin-capsuled I-131, within 3 days after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also, consider a thyroid burden assay for patient care personnel after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. Do not release any patient until either the exposure rate from the patient is less than 7 millirem per hour at 1 meter or the retained radioactivity is less than 33 millicuries. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

a. Remove all absorbent paper, and place it in the appropriate container.

b. Transfer all containers to a decay-in-storage or decontamination area.

c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2.

d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Exhibit 7,"Radiation Safety Checklist for Iodine Therapy over 33 Millicuries," may also be helpful to you.

902 KAR 100:072. Use of radionuclides in the health arts. Sections 13., 22., 27., 33., 34., 35., and 73.

Section 13. Written Directives. (1) A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (Thirty (30) microcuries (μCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

(a) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record.

(b) A written directive shall be prepared within forty-eight (48) hours of the oral directive.

(2) The written directive shall contain the patient or human research subject's name and the following information:

(a) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(b) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(d) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(e) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(f) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

1. Before implantation: treatment site, the radionuclide, and dose; and

2. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(a) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable. The oral revision shall be documented as soon as possible in the patient's record.

(b) A revised written directive shall be signed by the authorized user within forty-eight (48) hours of the oral revision.

(4) The licensee shall retain a copy of the written directive for three (3) years.

Section 22. Determination of Dosages of Unsealed Radioactive Material for Medical Use. (1) A licensee shall determine and record the activity of each dosage before medical use.

(2) For a unit dosage, this determination shall be made by:

(a) Direct measurement of radioactivity; or

(b) A decay correction, based on the activity or activity concentration determined by:

1. A manufacturer or preparer licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058, or U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements; or

2. An NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

(3) For other than unit dosages, this determination shall be made by:

(a) Direct measurement of radioactivity;

(b) Combination of measurement of radioactivity and mathematical calculations; or

(c) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 902 KAR 100:040 and 902 KAR 100:058, or U.S. Nuclear Regulatory Commission, or equivalent requirements.

(4) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty (20) percent.

(5) A licensee shall retain a record of the dosage determination for three (3) years. The record shall contain:

(a) The radiopharmaceutical;

(b) The patient's or human research subject's name, or identification number if one (1) has been assigned;

(c) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

(d) The date and time of the dosage determination; and

(e) The name of the individual who determined the dosage.

Section 27. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material. (1) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five (5) mSv (fife-tenths (0.5) rem). NUREG-1556, Vol. 9 (draft), "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding five (5) mSv (0.5 rem).

(2) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one (1) mSv (one-tenth (0.1) rem). If the total effective dose equivalent to

Attachment 3

a nursing infant or child could exceed one (1) mSv (one-tenth (0.1) rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(a) Guidance on the interruption or discontinuation of breast-feeding; and

(b) Information on the potential consequences, if any, of failure to follow the guidance.

(3) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with this section, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered;

(b) Using an occupancy factor less than 0.25 at one (1) meter;

(c) Using the biological or effective half-life; or

(d) Considering the shielding by tissue.

(4) A licensee shall retain a record that the instructions were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five (5) mSv (five-tenths (0.5) rem).

(5) The records required by subsections (3), and (4) of this section shall be retained for three (3) years after the date of release of the individual.

(6) A report shall be filed in accordance with Section 17 of this chapter and submitted to the cabinet if a dose greater than 50 mSv (5 rem) is received by an individual from a patient released under this section.

Section 33. Use of Unsealed Radioactive Material for Which a Written Directive is Required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(1) Obtained from a manufacturer or preparer licensed under 902 KAR 100:040 or 902 KAR 100:058 of this chapter, or U.S. Nuclear Regulatory Commission, or equivalent agreement state requirements;

(2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 70 or 71 of this administrative regulation or an individual under the supervision of either as specified in Section 12 of this administrative regulation;

(3) Obtained from and prepared by a cabinet, U.S. Nuclear Regulatory Commission or another agreement state licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Section 34. Safety Instruction. (1) In addition to 902 KAR 100:165, a licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for the patient or the human research subjects receiving radiopharmaceutical therapy and hospitalized for compliance with Section 27 of this administrative regulation. To satisfy this requirement, the instruction shall describe the licensee's procedures for:

(a) Patient or human research subject control;

(b) Visitor control:

1. Routine visitation to hospitalized individuals in accordance with 902 KAR 100:019, Section 10(1)(a) of this chapter; and

2. Visitation authorized in accordance with 902 KAR 100:019, Section 10(3) of this chapter;

(c) Contamination control;

(d) Waste control; and

(e) Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(2) A licensee shall retain a record of individuals receiving safety instructions required by Sections 34, 40, and 49 of this administrative regulation for three (3) years. The record shall include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Section 35. Safety Precautions. (1) For each patient or human research subject who cannot be released under Section 27 of this administrative regulation a licensee shall:

(a) Quarter the patient or the human research subject either in:

1. A private room with a private sanitary facility; or

2. A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under Section 27 of this administrative regulation;

(b) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign:

(c) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(d) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(2) A licensee shall notify the radiation safety officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies

Section 73. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). Except as provided in Section 68 of this administrative regulation the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3) of this section and whose certification has been recognized by the cabinet, U.S. Nuclear Regulatory Commission or another agreement state;

(2) Is an authorized user under Section 71(1), 71(2) of this administrative regulation for uses listed in Section 70(2)(a)2.g.(ii) of this administrative regulation U.S. Nuclear Regulatory Commission or equivalent agreement state requirements; or

(3)(a) Has successfully completed eighty (80) hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology;

(b) Has work experience, under the supervision of an authorized user who meets the requirements in Section 71(1), 71(2), 73 of this administrative regulation U.S. Nuclear Regulatory Commission or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in Section 71(2) of this administrative regulation have experience in administering dosages as specified in Section 71(2)(a)2.g.(i) of this administrative regulation. The work experience shall involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in subsection (3) paragraphs(a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under Section 33 of this administrative regulation. The written certification shall be signed by a preceptor authorized user who meets the requirements in Section 71(1), 71(2), 73 of this administrative regulation U.S. Nuclear Regulatory Commission or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in Section 71(2) of this administrative regulation shall have experience in administering dosages as specified in 902 KAR 100:072, Section 70(2)(a)2.g.(ii).

Inspection Report – Medical
Radiopharmaceutical Therapy

Materials / Facilities C NC N/A

Isotopes Used	*Activity Range*	*Form*
_____	_____	_____
_____	_____	_____
_____	_____	_____

Storage facilities as described in license: _____

_____

Receipt / Transfer (902 KAR 100:019, Section 28) C NC N/A

Receipt

Written procedures _____

Surveys performed _____

Procedures followed _____

Procedures for after hours _____

Shipping

Packaged _____

Marked _____

Labeled _____

Shipping papers _____

Surveys _____

Disposal Method (902 KAR 100:072, Section 28) C NC N/A

Describe (including linens, utensils, gloves, other) _____

_____

_____

Storage area _____

Surveys performed _____ Held for T½ _____

Information recorded: _____ date of disposal, _____ date in storage, _____ radionuclide
_____ model & SN, _____ bkg, _____ dose rate @ surface
_____ name of individual

Surveys (902 KAR 100:072, Section 35) C NC N/A

Room and adjoining areas _____

Materials and items removed from patient's room _____

Room prior to re-assignment (200 dpm or less) _____

Records _____
(time, date, areas, dose rates, instrument, surveyor)

Attachment 4

Handling Procedures	C	NC	N/A
Patient assigned private room / bath			
Preparation of room (to prevent contamination). Describe:			
Opening area has ventilation system (liquid iodine)			
Personnel protective equipment (gloves, coats, tongs, etc.)			
Disposable items used (utensils, bedpans, etc.)			
Method of transport (material and patient)			

Postings & Other Instructions (902 KAR 100:072, Section 35)	C	NC	N/A
Room posted CRM			
Note on patient's door/chart regarding visitors			
Nursing instructions			
Release criteria of patients:			
Instructions to patients upon release:			

Personnel Training (902 KAR 100:072, Section 34)	C	NC	N/A
Oral and written instructions			
Initial training includes all appropriate topics			
Annual refresher training			
Required information recorded			

Survey Instrument	C	NC	N/A
Instrument(s) and ranges			
Calibrated by _____ Frequency			

Personnel Dosimetry	C	NC	N/A
Determine of dose to:			
Handling personnel (extremity dose also)			
Ancillary personnel (nursing, others)			
Describe bioassay program and results (liquid iodine):			

INSTRUCTIONS TO POST-THYROIDECTOMY OUTPATIENTS WHO HAVE RECEIVED THERAPY WITH RADIOACTIVE IODINE

Patient Name:_____ MR #: _____

- You may ride home in a vehicle with an adult driver. No one under 16 years and no pregnant or potentially pregnant person should be in the vehicle. Sit as far from other people in the vehicle as possible.
- Sleep alone for the next seven days. There should be no kissing or intimate contact during this period.
- Stay at least six feet away from adults over 45 years of age and at least ten feet from younger people, especially children and pregnant women for the next seven days, except for brief periods of no more than 15 minutes each day as necessary.
- After the first week stay at least three feet from adults over 45 years and six feet from younger people for an additional seven days. Then you may resume normal activities.
- If you have a baby, or are caring for one, you can do all the things necessary for the baby's care. However, you should not have the baby sit on your lap or hold the baby close to your body for more than a few minutes a day for the first ten days.
- If you are breast-feeding your baby, you must stop, because radioactive iodine is secreted in breast milk. Failure to stop breast feeding may cause the baby to develop hypothyroidism, which may cause severe abnormalities in physical and mental development.
- Wash your hands with soap and plenty of water each time you go to the toilet.
- Keep the toilet especially clean. Flush it two or three times after each use.
- Rinse the bathroom sink, tub and shower thoroughly after each use for the first two days.
- Drink plenty of liquids such as water or juices. This will cause you to urinate more frequently, and make the radioiodine leave your body faster.
- Use separate (or disposable) eating utensils for the first two days and wash then separately. If non-disposable utensils are used, do not put them in a dishwasher.
- Use separate towels and washcloths and launder your towels, bed linens and underclothing separate from that of other family members for the first week.

I have read and understand the above instructions as explained to me by _____.

_____ Date: _____

Patient signature

Attachment 5

I-131 Doses > 30 mCi

Post I-131 administration patient information

Name:	Number:	Date:
Radiologist:	Isotope: I-131	Amount: _____ mCi

You are receiving a therapeutic dose of radioactive iodine for treatment of your thyroid. The radioactive material that does not stay in your thyroid will be excreted through urine, bowels, blood, saliva, and sweat. Radiation exposure to others will come from your being around other people and any bodily fluids that may be transferred. To keep exposure to others at a minimum, please follow the instructions listed below:

- Drink plenty of fluids the first few days after treatment to flush out that radioactive material that does not stay in your thyroid.
- Suck on lemon drops to help increase salivation.
- Avoid intimate contact (intercourse, kissing) for 5 days.
- Sleep in a separate area from other people for 5 days.
- Keep your distance from others greater than 3 feet for 5 days
- Wash your hands thoroughly after eating and using the restroom for 4 days
- Use a separate bathroom for 3 days if possible; sit down to urinate and flush the toilet at least twice for 4 days. Shower daily and allow the water to run for 3-4 minutes after you are finished to help cleanse the shower.
- Do not place infants at your neck level for 5 days
- Sleep in a separate area from other people for 5 days.
- Separately launder bedding and clothes used for 5 days.
- Do not share utensils and dishes; wash in a dishwasher or wash separately for 5 days.
- Use a new toothbrush after 7 days.
- If you have small children at home, avoid direct contact with them for 5 days; consider having children stay with relatives.
- No Breastfeeding. Breastfeeding should not resume for 12 months. Preventions for pregnancy should be used for 6 months.

I have read and understood the above suggestions.

_____ _____

Patient signature Date

902 KAR 100:019. Standards for protection against radiation. Sections 39. and 40.
902 KAR 100:072. Use of radionuclides in the health arts. Section 17.

902 KAR 100:019. Standards for protection against radiation. Sections 39. and 40.

Section 39. Notification of Incidents. (1) Immediate notification. A licensee or registrant shall immediately report an event involving radioactive material possessed by the licensee or registrant that may have caused, or threatens to cause, one (1) or more of the following conditions:

(a) An individual may receive:

1. A total effective dose equivalent of twenty-five (25) rems (0.25 Sv) or more;
2. An eye dose equivalent of seventy-five (75) rems (0.75 Sv) or more; or
3. A shallow-dose equivalent to the skin or extremities of 250 rads (two and five-tenths (2.5) Gy) or more;

(b) The release of radioactive material, inside or outside of a restricted area; so that, had an individual been present for twenty-four (24) hours, the individual may have received an intake five (5) times the occupational annual limit on intake. The provisions of this paragraph shall not apply to locations in which personnel are not normally stationed during routine operations, such as in hot-cells or process enclosure;

(c) A loss of one (1) working week or more of the operation of facilities affected; or

(d) Damage to property in excess of $200,000.

(2) Twenty-four (24) hour notification. A licensee or registrant shall, within twenty-four (24) hours of discovery of the event, report an event involving loss of control of licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or shall threaten to cause, one (1) or more of the following conditions:

(a) An individual to receive, in a period of twenty-four (24) hours:

1. A total effective dose equivalent exceeding five (5) rems (0.05 Sv);
2. An eye dose equivalent exceeding fifteen (15) rems (0.15 Sv); or
3. A shallow-dose equivalent to the skin or extremities exceeding fifty (50) rems (five-tenths (0.5) Sv);

(b) The release of radioactive material, inside or outside of a restricted area; so that, had an individual been present for twenty-four (24) hours, the individual may have received an intake in excess of one (1) occupational annual limit on intake. The provisions of this paragraph shall not apply to locations in which personnel are not normally stationed during routine operations, such as in hot-cells or process enclosures;

(c) A loss of one (1) day or more of the operation of facilities affected; or

(d) Damage to property in excess of $2,000.

(3) A licensee or registrant shall prepare and file a report with the cabinet as required by this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(4) Licensees or registrant shall make reports required by this section to the cabinet by:

(a) Telephone;

(b) Telegram;

(c) Mailgram; or

(d) Facsimile.

(5) The provisions of this section shall not include doses that result from planned special exposures that are within the limits for planned special exposures, and are reported under Section 41 of this administrative regulation.

Section 40. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits. (1) Reportable events. In addition to the notification required by Section 39 of this administrative regulation, a licensee or registrant shall submit a written report within thirty (30) days after learning of one (1) or more of the following occurrences:

(a) An incident for which notification shall be required by Section 39 of this administrative regulation; or

(b) Doses in excess of one (1) of the following:

1. Occupational dose limits for adults in Section 3 of this administrative regulation;
2. Occupational dose limits for a minor in Section 8 of this administrative regulation;
3. Limits for an embryo or fetus of a declared pregnant woman in Section 9 of this administrative regulation;
4. Limits for an individual member of the public in Section 10 of this administrative regulation;
5. Applicable limit in the license or registration;
6. ALARA constraints for air emissions established under Section 2(4); or

(c) Levels of radiation or concentrations of radioactive material in:

1. A restricted area in excess of an applicable limit in the license or registration; or
2. An unrestricted area in excess of ten (10) times an applicable limit set forth in this administrative regulation, the license, or the registration, regardless of exposure of an individual in excess of the limits in Section 10 of this administrative regulation occurs; or

(d) For a person, agency, or licensee subject to the provisions of 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or conditions related to those standards.

(2) Contents of reports.

(a) A report required by subsection (1) of this section shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

1. Estimates of each individual's dose;
2. The levels of radiation and concentrations of radioactive material involved;
3. The cause of the elevated exposures, dose rates, or concentrations; and
4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints and environmental standards, and associated license or registration conditions.

(b) A report filed under subsection (1) of this section shall include for each individual exposed:

1. Name of the individual;
2. Social Security number; and
3. Date of birth.

Attachment 7

(c) The report shall be prepared so that information is stated in a separate and detachable part.
(d) With respect to the limit for the embryo or fetus, the identifiers shall be of the declared pregnant woman.
(3) A licensee or registrant who makes a report under subsection (1) of this section shall submit the report, in writing, to the Manager of the Radiation Control Branch, Department for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.

902 KAR 100:072. Use of radionuclides in the health arts. Section 17. and Section 27.

Section 17. Report and Notification of a Dose Greater Than Fifty (50) mSv (5 rem) to an Individual From a Patient Released Under Section 27 of this Chapter. (1) A licensee shall notify the Cabinet for Health and Family Services, Radiation Health and Toxic Agents Branch and file a report, if required, for any dose greater than fifty (50) mSv (5 rem) total effective dose equivalent that an individual receives from a patient released under this section.

(2) The licensee shall notify by telephone the Cabinet for Health and Family Services, Radiation Health and Toxic Agents Branch (502) 564-3700 no later than the next calendar day after the licensee becomes aware of an event that requires a report in subsection (1) of this section.
(3) The licensee shall submit a written report to the Cabinet for Health and Family Services, Radiation Health and Toxic Agents Branch, 275 East Main Street, Frankfort, Kentucky 40601, within fifteen (15) days after the licensee becomes aware of an event that requires a report in subsection (1) of this section. The individual(s) receiving this dose from an event as described in subsection (1) is hereafter referred to as identified exposed individual(s). The written report shall include:
(a) The name of the licensee;
(b) The estimated dose(s) to the exposed individual(s);
(c) A brief description of the event;
(d) Why the event occurred;
(e) What actions, if any, have been taken or are planned to prevent recurrence; and
(f) Certification that the licensee notified the identified exposed individual(s).
(4) The report shall not contain the names of the identified exposed individual(s) or the individual released under subsection (1) of this section or any other information that could lead to the identification of the exposed individual(s) or the individual released under subsection (1) of this section.
(5) The licensee shall provide notification of the event to the identified exposed individual(s) no later that twenty-four (24) hours after the licensee becomes aware of an event that would require reporting under subsection (1) of this section.
(6) The licensee shall provide the identified exposed individual(s) with a copy of the report submitted to the cabinet.

Section 27. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material. (1) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five (5) mSv (fife-tenths (0.5) rem). NUREG-1556, Vol. 9 (draft), "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding five (5) mSv (0.5 rem).

(2) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one (1) mSv (one-tenth (0.1) rem). If the total effective dose equivalent to a nursing infant or child could exceed one (1) mSv (one-tenth (0.1) rem) assuming there were no interruption of breast-feeding, the instructions shall also include:
(a) Guidance on the interruption or discontinuation of breast-feeding; and
(b) Information on the potential consequences, if any, of failure to follow the guidance.
(3) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with this section, if the total effective dose equivalent is calculated by:
(a) Using the retained activity rather than the activity administered;
(b) Using an occupancy factor less than 0.25 at one (1) meter;
(c) Using the biological or effective half-life; or
(d) Considering the shielding by tissue.
(4) A licensee shall retain a record that the instructions were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five (5) mSv (five-tenths (0.5) rem).
(5) The records required by subsections (3), and (4) of this section shall be retained for three (3) years after the date of release of the individual.
(6) A report shall be filed in accordance with Section 17 of this chapter and submitted to the cabinet if a dose greater than 50 mSv (5 rem) is received by an individual from a patient released under this section.

Nal Ablation

Patient Specific Dose Calculations **Patient** _____

Equation =[34.6(Gamma)(A)]/d^2{E1*Tp*Fo*(1 -e^(-.693*t/Tp)) + (e^(-.693*t/Tp))*E2*F1*T1 + (e^(-.693*t/Tp)) * E2*F2*T2}

	Actual	Equation	
Solved:	1.142	34.6(Gamma)(A)]/d^2	*
	4.824	E1*Tp*Fo	*
	0.028	1 -e^(-.693t/Tp)	+
	0.074	(e^(-.693t/Tp))*E2*F1*T1	+
	0.089	(e^(-.693t/Tp)) * E2*F2*T2	=

Accumulated dose to members of public = 0.340 rem

34.6	Conversion factor of 24 hrs/day times the total int. of decay (1.44)
2.2 Gamma	Exposure tate constant R/mCi-hr @ 1 cm
150 A	**Initial Activity at start of time interval**
100 d	Distance in centimeters
0.75 E1	Occupancy factor for the first 8 hours
0.25 E2	**Occupancy factor from 8 hours to total decay**
0.95 F1	Extrathyroidal uptake fraction
0.05 F2	Thyroidal Component
0.32 T1	Effective half-life for extrathyroidal component
7.3 T2	Effective half-life for thyroidal component
0.33 t	First 8 hours
8.04 Tp	Physical Half Life
0.8 Fo	Initial uptake fraction

E1 = always 0.75 occupancy
E2 = .125 if live alone, .25 if normal contact, .75 if extended care

Calculation based on information taken from Nuclear Regulatory Guide 8.39

Attachment 6

OUTPATIENT I-131 THERAPY FOR POST-THYROIDECTOMY CANCER PATIENTS

Release Criteria Based on patient specific dose calculations above 33 mCi

Dose = 7.6*A(0)*(0.136656+1.6956*TU.0777)
Dose is the dose equivalent from adninistratiion to total decay
A(0) is the administered activity in mCi
TU is the thyroid uptake

Assumptions:
Treatment is post-thyroidectomy
Physical decay only during first 8 hours for 80% of oral dose
Two-compartment model beginning 8 hours post-administration
Extra-thyroidal effective half-time = 0.32 days
Thyroidal effective half-time = 7.3 days
75% occupancy at one meter during first 8 hours
25% occupancy at one meter from 8 hours to total decay

Patient name: Jane Doe

Hospital Number: 1234

Administered dose in mCi:** 100.0 Thyroid uptake*: 5.00 %

The calculated total dose equivalent to another individual from proximity to this patient is: 227 mrem.

FOR THE PATIENT TO BE RELEASED, THE DOSE EQUIVALENT TO ANOTHER INDIVIDUAL MUST NOT EXCEED 500 MREM.

Date/Time of release: 3/23/08 12:40 PM

Technologist: Michelle Eckart, CNMT

* If a measured uptake is available, insert it. Otherwise use the case-specific value of 5.0%.

I-131 THERAPY FOR ADMITTED POST-THYROIDECTOMY CANCER PATIENTS

Release Criteria Based on: Patient Specific Dose Calculations above 33 mCi

Dose = A(0)*7.612*(0.1577*(1-TU)*0.5^((t-0.333)/0.32)+1.884*TU*0.5^((t-0.333)/7.3))

Dose is the dose equivalent from the time of patient release to total decay
t is the time of patient release in days post-administration
A(0) is the administered activity in mCi
TU is the thyroid uptake

Assumptions:
Treatment is post-thyroidectomy
Physical decay only during first 8 hours post administration
Two-compartment model beginning 8 hours post-administration
Extra-thyroidal effective half-time = 0.32 days
Thyroidal effective half-time = 7.3 days
75% occupancy at one meter during first 8 hours post-release
25% occupancy at one meter from 8 hours post-release to total decay

Patient name: _____

Hospital Number: _____

Administered dose in mCi: _____ Thyroid uptake*: _____ %

Date & time of administration (M/DD/YR XX:YY am): _____

Date & time of proposed release: _____

Hours post-administration (must be more than 8 hours): _____

The calculated total dose equivalent to another individual from proximity to this patient is: #VALUE! mrem.

FOR THE PATIENT TO BE RELEASED, THE DOSE EQUIVALENT TO ANOTHER INDIVIDUAL MUST NOT EXCEED 500 MREM.

Date/Time of release: _____

Technologist: _____

* If a measured uptake is available, insert it. Otherwise use the case-specific value of 0.05.